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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,304	06/27/2003	Michel J. N. Cormier	33392-714.201	8982

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EXAMINER
ALSTRUM ACEVEDO, JAMES HENRY

ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/608,304

Applicant(s)

CORMIER ET AL.

Examiner

James H. Alstrum-Acevedo

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-23 are pending. Applicants amended claims 9, 11, 13-14, 18-20, and 22-23. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on September 29, 2006 is acknowledged.

Specification

The objection to the specification due to the improper use of the trademarks PLURONIC® [00022] and TWEEN® [00022] **is withdrawn**, because said trademarks are now correctly capitalized throughout the specification as a result of Applicants' amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 9, 11, 13, 18, and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicants' amendments to said claims to replace trademarks with equivalent chemical names.

Response to Arguments

Applicant's arguments, see page 9, filed September 29, 2006, with respect to claims 9, 11, 13, 18, and 20 have been fully considered and are persuasive. The rejection of claims 9, 11, 13, 18, and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

Art Unit: 1616

particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-3, 5-7, 12, 15-16, and 21 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) **is maintained** for the reasons of record set forth on pages 4-6 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicant's traversal of this rejection is based on their assertions that Trimmer does not teach a method of treating the surface of microprotrusions, such as rinsing with a wetting agent as taught in claim 1 of the instant application. The Examiner respectfully disagrees. Applicants admitted on the record (see page 12, 4th paragraph of the remarks/arguments) that Trimmer does teach a method of microprotrusions. Applicants then asserted that the method taught by Trimmer did not read on those claimed by Applicants, because the ethanol soak/water rinse taught by Trimmer does not constitute a rinse with a wetting agent. This is incorrect, because the term "wetting agent" is not defined in the specification to exclude liquids that could wet a surface. Applicants' description of wetting agents to include amphiphilic molecules is not a definition and thus does not set forth clear metes and bounds for this term (see [0021]-[0022]). Therefore, a person of ordinary skill in the art would conclude that a reasonable broad interpretation of the term "wetting agent" includes liquids that could "wet" a surface. It is also noted that Applicants' method incorporating the pretreatment of a surface is not limited to chemical etching. Applicants' have not defined the term "chemical treatment" and therefore a reasonably broad interpretation of this term would not be limited to treatments that pit the surface. As a result, soaking in ethanol reads on chemical

Art Unit: 1616

treatment, because ethanol is a chemical. Regarding claims 5-6, it would have been obvious to a person of ordinary skill in the art that techniques utilized to clean silicon in preparation of microprojections would also be reasonably expected to serve a similar purpose prior to coating, if needed. Furthermore, it is the Examiner's position that the ordinary skilled artisan would have realized that techniques used in preparing microprojections from silicon, as taught by Trimmer, such as cleaning with a mixture of HCl and hydrogen peroxide (i.e. a wetting agent); (2) oxidation by heating in an electrically heated quartz furnace; (3) etching in buffered hydrofluoric acid; (4) cascade rinsing; and (5) etching in an aqueous solution of KOH (i.e. an alkaline solution) could also be used to clean the surfaces of the fabricated microprojections prior to coating. This would have been obvious to the ordinary skilled artisan because these techniques yield etched silicon surfaces (microprojections) and said etched surfaces could only result from the removal of silicon, along with any undesirable surface contaminants (e.g. organics and/or native oxide) from the surface. In other words, it would have been apparent to the ordinary skilled artisan that exposure of the fabricated microprojections to any of the methods taught by Trimmer, albeit for shorter periods of time than those required in fabrication, would remove extraneous impurities and yield a "clean" surface ideally suited for coating. Regarding claim 12, it would also have been obvious to a person of ordinary skill that the term "biological material," which Trimmer teaches can be applied as a film or coating onto his invented microprobes, includes proteins and peptides. Proteins and peptides are art recognized biological materials. A skilled artisan would have had a reasonable expectation of successfully forming a film of the biological materials taught by Trimmer on his invented microprobes, because the step of drying a

coating formulation is conventional. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

In summary, it is the Examiner's position that an ordinary skilled artisan at the time of the instant invention would have concluded that claims 1-3, 5-7, 12, 15-16, and 21 are *prima facie* obvious over the teachings of Trimmer et al. (WO 96/10630).

The rejection of claims 8-10, 13, 17-19, and 22 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Baum (U.S. Patent No. 6,294,515) **is maintained** for the reasons of record set forth on pages 6-8 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that (1) Trimmer allegedly does not teach a method of treating the surface of microprotrusions, such as rinsing with a wetting agent as taught in claim 1 of the instant application, and that this deficiency is not cured by the teachings of Baum and (2) the inclusion of a wetting agent taught by Baum in the drug coating solution of Trimmer does not capture the steps of Applicants' claim because surface treatment occurs prior to application of a drug coating solution.

The Examiner respectfully disagrees with Applicants' traversal arguments. Traversal argument (1) was addressed above in the instant office action and is reiterated here, but not reproduced for conciseness. Regarding the second traversal argument, it is noted that

Art Unit: 1616

Applicants' claim language does not preclude the inclusion of wetting agents in the coating formulation nor prohibit the combination of the step of rinsing with a wetting agent with the steps of providing and applying a coating formulation. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

In summary, it is the Examiner's position that an ordinary skilled artisan at the time of the instant invention would have concluded that claims 8-10, 13, 17-19, and 22 are *prima facie* obvious over the combined teachings of Trimmer et al. (WO 96/10630) and Baum (U.S. Patent No. 6,294,515).

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Heinz et al. (US 2002/0012741) **is maintained** for the reasons of record set forth on pages 8-9 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that (1) Trimmer allegedly does not teach a method of treating the surface of microprotrusions, such as rinsing with a wetting agent as taught in claim 1 of the instant application, and that this deficiency is not cured by the teachings of Heinz and (2) it would allegedly not be obvious to utilize a plasma treatment method as a microprobe pre-conditioning step based on the teachings of Heinz.

The Examiner respectfully disagrees with Applicants' traversal arguments. Traversal argument (1) was addressed above in the instant office action and is reiterated here, but not reproduced for conciseness. Regarding the second traversal argument, it is noted that plasma treatment is a conventional step in the pre-conditioning of a surface (Heinz). The surfaces Heinz teaches as being pre-treated with plasma include the surfaces of a syringe (i.e. a medical product). It is commonly known that syringes are made of glass and that glass is derived from silicon materials. An ordinary skilled artisan would have had a reasonable expectation that pre-conditioning via plasma treatment of surfaces of silicon-based materials such as the glass in a syringe could successfully be applied to the microprotrusions taught by Trimmer, because Trimmer teaches that microprotrusions can be made from silicon wafers using plasma treatment. An ordinary skilled artisan would have been motivated to modify the teachings of Trimmer to utilize plasma treatment as an alternative or even supplemental pre-conditioning treatment prior to application of a coating formulation, because this is an art recognized conventional step. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

In summary, it is the Examiner's position that an ordinary skilled artisan at the time of the instant invention would have concluded that claim 4 is *prima facie* obvious over the teachings of Trimmer et al. (WO 96/10630) and Heinz et al. (US 2002/0012741).

The rejection of claims 11, 14, 20, and 23 under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. (WO 96/10630) as applied to claims 1-3, 5-7, and 15-16 above, and further in view of Jain et al. (U.S. Patent No. 4,505,890) **is maintained** for the reasons of record set

Art Unit: 1616

forth on pages 9-11 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that (1) Trimmer allegedly does not teach a method of treating the surface of microprotrusions, such as rinsing with a wetting agent as taught in claim 1 of the instant application, and that this deficiency is not cured by the teachings of Jain and (2) the inclusion of HPMC taught by Jain into a drug coating solution of Trimmer does not capture the steps of Applicants' claim because surface treatment occurs prior to application of a drug coating solution.

The Examiner respectfully disagrees with Applicants' traversal arguments. Traversal argument (1) was addressed above in the instant office action and is reiterated here, but not reproduced for conciseness. Regarding the second traversal argument, it is noted that Applicants' claim language does not preclude the inclusion of wetting agents (e.g. HPMC) in the coating formulation nor prohibit the combination of the step of rinsing with a wetting agent with the steps of providing and applying a coating formulation. Applicants' data in the specification was noted. Applicants have not claimed any unexpected or surprising results.

In summary, it is the Examiner's position that an ordinary skilled artisan at the time of the instant invention would have concluded that claims 11, 14, 20, and 23 are *prima facie* obvious over the combined teachings of Trimmer et al. (WO 96/10630) and Jain et al. (U.S. Patent No. 4,505,890).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-3, 5-7, and 15-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,855,372 (USPN '372) in view of Trimmer et al. (WO 96/10630) **is maintained** for the reasons of record set forth on pages 11-12 of the previous office action mailed on June 14, 2006 and further articulated below.

Response to Arguments

Applicant's arguments filed September 29, 2006 have been fully considered but they are not persuasive. Applicants traversal of this rejection is based on their assertions that none of the claims of USPN '372 teach a step of treating the surface of one or more microprotrusions selected from the group including rinsing with a wetting agent and that the teachings of Trimmer do not cure this deficiency. The Examiner respectfully disagrees, because, as Applicants'

admitted and as the Examiner has further articulated above in the instant application, Trimmer does teach a method of pre-treating a surface.

In summary, it is the Examiner's position that an ordinary skilled artisan at the time of the instant invention would have concluded that claims 1-3, 5-7, and 15-16 are *prima facie* obvious on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the cited claims of U.S. Patent No. 6,855,372 (USPN '372) in view of Trimmer et al. (WO 96/10630).

The provisional rejection of claims 1-3 and 15-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-30 and 33-38 of copending Application No. 10/674,626 (copending '626) is withdrawn, per Applicants' persuasive arguments.

Response to Arguments

Applicant's arguments, see pages 15-16, filed September 29, 2006, with respect to claims 1-3 and 15-16 have been fully considered and are persuasive. The rejection of claims 1-3 and 15-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-30 and 33-38 of copending Application No. 10/674,626 (copending '626) is withdrawn.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are considered to be pertinent because these demonstrate the cleaning of silicon surfaces using chemical etching and/or plasma treatment: Kitamura et al. (U.S. Patent No. 5,066,630); Ohmi, T. et al. *J. Electrochem. Soc.* **1993**, *140*(3), pp 804-810; and Kim, C.-K. et al. *Korean J. of Chem. Eng.* **1996**, *13*(3), pp 328-330.

Claims 1-23 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571)

Art Unit: 1616


272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0664. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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